

MAY 23 2012

Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Huizhou Foryou Medical Devices Co., Ltd.
No.1, Shangxia North Road, Dongjiang Hi-Tech Industry Park,
Huizhou, Guangdong Province, China
Tel: (086) 0752-5302013
Submitter's FDA Registration Number: 3007735241

US Agent and Contact Person

Chengyu Shen
Manton Business and Technology Services
5 Carey Street
Pennington, NJ 08534
Tel: 608-217-9358
Email: cysen@aol.com

Date of Summary: Sept 22, 2011

Device Name:

Trade Name:	Suntouch Topical Hemostatic Dressing
Common Name:	Hemostatic Wound Dressing
Classification Name:	Dressing; wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Predicate Device Information:

- (1) K072681, "Bloodstop Hemostatic Gauze; Ix Hemostatic Gauze", manufactured by "Lifescience Plus, Inc" located in Mystic, CT 06355
- (2) K071578, "Bloodstop And Bloodstop IX Hemostatic Gauze", manufactured by "Lifescience Plus, Inc" located in Mystic, CT 06355

Device description:

The Suntouch Topical Hemostatic Dressing is made from regenerated cotton cellulose, chemically treated to become water-soluble. When contacting blood and exudates, they expand into clear gel, thereby adhering and creating pressure to seal the wound.

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The gauzes are sold in the following forms: Sheet, rolls, and pack (four layers)

Table 5.1 List of all Forms and Sizes Involved in this Submission

Design Form	Size
Sheet	25 x 25 mm, 50 x 30 mm, 50 x 50 mm, 50 x 70 mm, 100 x 100 mm, 120 x 80 mm, 160 x 140 mm, 200 x 100 mm Other sizes requested by distributors
Roll	12 x 5 mm (Width x diameter) Other sizes requested by distributors
Pack (four layers)	11 x 11 mm 19x19 mm Other sizes requested by distributors

All gauze are sterilized and sold directly to users after sterilization by radiation using conditions validated following ISO 11137-2: 2006.

Intended Use:

Prescription:

Suntouch Topical Hemostatic Dressing is indicated for the management of topical wounds and to temporary control of external surface bleeding.

All gauze are sterilized and sold directly to users after sterilization by radiation using conditions validated following ISO 11137-2: 2006.

Over the Counter:

Suntouch Topical Hemostatic Dressing is indicated for temporary external topical bleeding of minor cuts, minor lacerations, and it is contraindicated for internal use.

All gauze are sterilized and sold directly to users after sterilization by radiation using conditions validated following ISO 11137-2: 2006.

Comparison to Predicate Devices

Suntouch Topical Hemostatic Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

- (1) K072681, "Bloodstop Hemostatic Gauze; 1x Hemostatic Gauze", manufactured by "Lifescience Plus, Inc" located in Mystic, CT 06355
- (2) K071578, " Bloodstop And Bloodstop IX Hemostatic Gauze", manufactured by "Lifescience Plus, Inc" located in Mystic, CT 06355

The following table shows similarities and differences of use, design, material, and processing methods between our device and the predicate devices.

Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K072681)	Predicate Device 1 (K071578)
Indication for Use	<p><u>Prescription:</u> Suntouch Topical Hemostatic Dressing is indicated for the management of topical wounds and to temporary control of external surface bleeding.</p> <p>All gauze are sterilized and sold directly to users after sterilization by radiation using conditions validated following ISO 11137-2: 2006.</p>	Non-absorbable hemostatic gauze for OTC, emergency and therapeutic use.	
	<p><u>Over the Counter:</u> Suntouch Topical Hemostatic Dressing is indicated for temporary external topical bleeding of minor cuts, minor lacerations, and it is contraindicated for internal use.</p>	It is used for the control of bleeding from the skin and other surface wounds where temporary control of bleeding is required.	Topical control of bleeding of minor cuts and abrasions of skin surface
	All gauze are sterilized and sold directly to users after sterilization by radiation using conditions validated following ISO 11137-2: 2006.		
Prescription/OTC	Prescription and OTC	Prescription	OTC
Mechanism	When contacting blood and exudates, they expand into clear gel, thereby adhering and creating pressure to seal the wound.	Same	Same
Materials	Regenerated cotton cellulose	Same (Identical Infrared Spectrum)	Same (Identical Infrared Spectrum)
Chemical Treatment	Oxidized and etherized to become water-soluble	Oxidized and etherized to become water-soluble	Oxidized and etherized to become water-soluble
Single Use	Yes	Yes	Yes
Sterile	Sterile	Sterile	Sterile

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Infrared Spectroscopy is a powerful technique in elucidate the structure of chemical materials. Each functional group inside a molecule has its unique infrared absorption, so each peak in an infrared spectrum is regarded as the “finger print” of a functional group inside the molecule.

We recorded the infrared spectra of Suntouch Topical Hemostatic Dressing and BloodStop Gauze and they are summarized below. The almost identical spectra indicated both devices are very similar in chemical structure.

Product	Infrared Spectrum
Suntouch Topical Hemostatic Dressing	
Predicate Device 1 (K071578)	

Therefore, Suntouch Topical Hemostatic Dressing and its predicate devices are both made from regenerated cotton cellulose, underwent the same chemical treatment to become water soluble, have same chemical structure, and utilize the same bleeding control mechanism. They are both indicated for temporary external topical bleeding.

The following table (Table 5.2) shows similarities and differences of the hemostatic performance between our device and the predicate devices. (Experimental details can be found in Section 19)

Table 5.2: Comparison of Hemostatic Performance of Suntouch and BloodStop Dressings

Description	Our Device	Predicate Device 1 (K072681)	Predicate Device 2 (K071578)
Average Stop Bleeding Time on Swine Neck Artery Wound (see Section 19 for test details)	55.0 minute (vs. 108.75 min for control dressing)	Same as Predicate Device 2 per BloodStop claim	65.0 minute (vs. 108.75 min for control dressing)
Average Blood Loss on Swine Neck Artery Wound (see Section 19 for test details)	82.6 gram (vs. 163.84 g for control dressing)	Same as Predicate Device 2 per BloodStop claim	81.9 gram (vs. 163.84 g for control dressing)
In Vitro Procoagulant Test (Internal Test Procedure)	Test Group Clog in 34 Second, Blank Control Group Does not Clog	Not tested	Not tested

Stop bleeding tests were conducted on swine neck artery wound and were conducted side by side with the predicate device. As shown from Table 5.2, times needed for Suntouch Dressing to stop bleeding, and the blood loss in 120 min period, are comparable to the predicate device. More details of tests are summarized in *Section 19*.

In Vitro Procoagulant Test was also conducted for our Suntouch Topical Hemostatic Dressing. Our device can rapidly clot the blood even under anti-coagulate agent, further demonstrated its effectiveness in controlling bleeding. More details of the test can be found in *Section 18*. There is no similar data available for predicate device for this test.

The following table (Table 5.3) shows similarities and differences of the biocompatibility performance between our device and the predicate devices.

Biocompatibility tests were conducted following procedures outlined in the respective consensus standards, and results for Suntouch Topical Hemostatic Dressing met all relevant requirements in the test standards, and are comparable to the predicate device. More details of biocompatibility tests are summarized in *Section 15*.

Table 5.3: Comparison of Biocompatibility Performance Testing

Description	Our Device	Predicate Device 1 (K072681)	Predicate Device 2 (K071578)
Cytotoxicity	No Toxic Effect (ISO10993-5)		
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	Biocompatible	Biocompatible
Systematic Toxicity	No Effect (ISO 10993-11)		
Pyrogenicity	No Effect (ISO 10993-11)		

A brief discussion of the non-clinical testing data that was submitted, referenced or relied on to demonstrate that the Subject Device is safe and effective, and whose performance meets the requirements of its user-defined acceptance criteria and intended uses:

Suntouch Topical Hemostatic Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11 (acute system toxicity and pyrogenicity). It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by radiation using conditions validated following ISO 11137-2: 2006. The product is safe and effective for its intended use.

A brief discussion of the clinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence.

Clinical data is not needed for wound dressing or for most devices cleared by the 510(k) process.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Suntouch Topical Hemostatic Dressing is substantial equivalent to its predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

MAY 23 2012

Huizhou Foryou Medical Devices Co., Ltd
% Manton Business and Technology Services
Chengyu Shen
Manager
5 Carey Street
Pennington, New Jersey 08534

Re: K112800

Trade/Device Name: Suntouch Topical Hemostatic Dressing
Regulation Class: Unclassified
Product Code: FRO
Dated: April 24, 2012
Received: April 24, 2012

Dear Chengyu Shen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

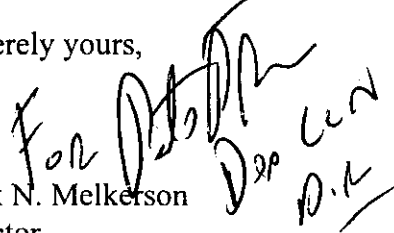
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use

Section 4: Indication for Use Statement

510(k) Number (if known): **K112800**

Device Name: Suntouch Topical Hemostatic Dressing

Indications for Use:

Prescription:

Suntouch Topical Hemostatic Dressing is indicated for the management of topical wounds and to temporary control of external surface bleeding.

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Over the Counter:

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All gauze are sterilized and sold directly to users after sterilization by radiation using conditions validated following ISO 11137-2: 2006.

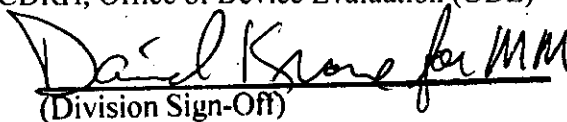
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112800